UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

DATE: February 10, 2010

SUBJECT: Label Amendment for Fresh Cab (EPA Reg. #: 82016-1), Containing 2.0% Fir Needle Oil (Active Ingredient). Review of Product Performance Study

Decision Number:	403501
DP Number:	360599
EPA File Symbol Number:	82016-1
Chemical Class:	Biochemical
PC Codes:	129035
Tolerance Exemption:	40 CFR 180.
MRID Numbers:	47611701

From: Manying Xue, Chemist
Clara Fuentes, Biologist
BPB/BPPD (7511P)

To: John Fournier, Regulatory Action Leader
BPB/BPPD (7511P)

Action Requested:

On behalf of EARTH-KIND, Inc. Pither Consulting, LLC has submitted an efficacy study (MRID 47943601) for Fresh Cab to support a label amendment to increase the interval of efficacy from 30 days to 100 days for Fresh Cab (EPA Reg. #: 82016-1) containing 2% of fir needle oil (the active ingredient). Fresh Cab has been classified as a biochemical which is proposed to be used to repel rodents in enclosed areas such as tractor cabs, electrical boxes, cabin cruisers, RV homes, and in non-living areas such attics, cellars, storage areas, garages, etc.

BPPD has reviewed and evaluated the study for the EP, Fresh Cab. The decisions are made to reflect the current OPP policies.

Recommendations and Conclusions

1. The submitted product performance study (MRID 47943601) does not support this label amendment to increase the interval of efficacy from 30 days to 100 days for Fresh Cab (EPA Reg. #: 82016-1). Based on the result, BPPD concludes that mice activity between the control room and treatment room was similar from 90 days to 100 days after Fresh Cab treatment.

2. The study is inconclusive due to lack of replications and independence among observations. The conclusion of this test is based in one observation (trial 2). More trial is needed to verify that this response is consistent among different populations of mice.

3. The observations are not independent of each other because they are all taken from the same mice. Furthermore, it is unknown how many mice were used at each trial. Therefore, it is impossible to generalize the results of this study to the population of mice because the results are derived from a sample, which size is unknown, and the sample is made up of the same mice that were tested over time. To improve the study, it is important to justify the size of the population sample. Different, rather than the same mice should be exposed to the treatment, and the treatment must be replicated more than twice, using different mice, to verify that the results are consistent.

4. Based on the results here reported, it seems that the treatment has no effect on the mice the first time they are exposed to it, even after 10 consecutive days of testing. Repellency was observed only at the second trial, when the same mice were exposed to the pouch again for a second time. These results indicate that the pouch is not effective at first encounter, and that it might take the same mice a long period of exposure or acclimation to the product to learn to avoid it.

5. Another way to improve the study design is by exposing mice to the treatments in a non-choice situation because if a more palatable source of food is available in the adjacent (control room), and the mice have been exposed to both repeatedly, learning to chose the best of the 2 rooms will be a contributing factor overestimating the efficacy of the product.

6. The registrant need to specify whether the test substance described as **various herbal ingredients** is the same as the proposed end use product for this registration.

7. Visual observation study does not support this label amendment. Visual counts were conducted for the control room and treatment room at approximately the same time twice a day to determine percent repellency during each trial. BPPD has concluded in the previous memo (M. Xue, 04/13/09) that "minimum three times (does not mean increasing sample size, which is number of mice tested)" are required for the observation study. BPPD also recommended that "observing the mice for a given

period of times (in minutes) every hour or half hour to come up with an average of time spent in one place or another". In addition, the number of mice tested was not reported. Apparently, the same mice were tested for entire duration of the test.

8. The submitted label is **UNACCEPTABEL.** The statement under EATH-KIND, Inc should be removed from the label which is misleading. The website and e-mail information should not be on the label.

Study Summaries

The purpose of this efficacy study was to determine the level of repellency of Fresh Cab Mouse Repellant for Storage Areas to wild house mice (Mus musculus) during the storage between 90 to 100 days. The deterrence packs were aged for 90 days at two intervals ten days apart. The deterrence packs were placed with the test system after aged 90 days. Two separate trials were completed with different deterrence packs and groups of the test system.

Materials and Methods

Test Substance

The test substance was formulated by Earth-Kind lnc./Crane Creek Gardens of various herbal ingredients that emit a scent thought to be unattractive to house mice. It is packaged in 2.5 oz., biodegradable pouches. The Fresh Cab packs used for the first trial started aging on July 6, 2009. The Fresh Cab packs used for the second trial started aging on July 16, 2009.

Method

The rooms were randomly selected to be either the control or treatment room. Pouches were placed on the floor in the center of the treatment room. The mice were placed into the study rooms the day before study day 0 of the 10-day exposure period. The morning of study day 0 of the 10-day exposure period a randomly selected Fresh Cab pack was presented in the treatment room. After approximately an hour had passed the first observation was recorded. Observations were made twice a day, the last observation being recorded the afternoon of the study day 10. After study day 10 the test system and test substance were removed, the study rooms were cleaned and prepared for the second trial. During the second trial, the control and treatment rooms were switched and the rooms were set up identically to the first trial.

Test System

The house mouse (Mus musculus) is the target species for the Fresh Cab. House mice were used for the test because of their wide distribution across North America, their propensity for being a commensally rodent, and their association with damage to house wares, vehicles, farm machinery, etc. Housing, Maintenance, and Group Assignment of the Test System Wild house mice were live trapped on nearby farms in Larimer County, Colorado using Sherman live traps between September 29, 2009 and October 1, 2009. The traps were baited with oats and peanut butter. The mice were transported in the Sherman traps placed inside a plastic container. The plastic container was transported by truck to Genesis Laboratories, Inc. The sex, age, and size of the mice varied.
The mice were removed from the Sherman live traps and randomly placed in holding tanks; the mice were treated for external parasites and observed by a veterinarian.
Two study rooms, approximately 252.96 ft^2 of floor area were used for the trials. The two study rooms were connected with a 12- inch section of 1.5 inch diameter PVC pipe that ran through the wall at the base of the floor. This allowed the mice free access to both rooms.

Environment

The mean minimum and maximum daily temperatures during the aging period (7/6/09 — 10/15/09) was 18.9 ± 1.8°C and 23.2 ± 2.0°C, respectively. The mean minimum and maximum relative humidity during this period were 33.6 ± 6.7% and 45.5 ± 8.8%, respectively. The mean minimum and maximum daily temperatures during the first trial were 13.7 ± 0.7°C and 18.5 ± 2.4°C, respectively. The mean minimum and maximum relative humidity during the first trial was 31.7 ± 2.3% and 35.5 ± 1.7%, respectively. The mean minimum and maximum daily temperatures during the second trial were 14.9 ± 0.9°C and 19.5 ± 0.8°C, respectively. The mean minimum and maximum relative humidity during the second trial was 33.4 ± 1.6% and 37.6 ± 6.7%, respectively.

Exposure Period Feed Consumption

On study day 0 of each trial 20 pieces of rodent diet were presented on two paper plates in each room. Ten pieces of the rodent feed were placed on each plate and the two plates were placed at opposite sides of each study room. Removal of feed from the plates was counted as an indirect index of rodent activity. Feed pieces were recorded as a means of measuring rodent activity and an indication as to where the mice were spending their time. Feed pieces removed from the plates were not retrieved and any plate that had been emptied was replenished with a recorded amount of feed.

Results and Discussion

Exposure period feed consumption data for trial 1 and trial 2 are presented in Table 1. At the beginning of each trial 20 food pieces were placed on two paper plates in each study room. The pieces of feed were counted in each room twice each day. Removal of feed

from the plates was counted as an indirect index of rodent activity and expressed as percent activity. A missing piece of food was considered to be evidence that the mice were spending time in the respective rooms.

Table 1 Repellency and Activities resulted from Fresh Cab (EPA Reg. #: 82016-1) Treatments.

	Samples	Total feed offered	Total removed	% Activities
Trial 1	Control	60	44	73
	Treatment	60	49	82
Trial 2	Control	20	16	80
	Treatment	50	47	94

Trial 1: During the exposure period for the first trial, a total 44 pieces were removed from the plates in the control room and 49 pieces were removed from the plates in the treatment room over the 10- day trial period. Percent activity in the control room and treatment room was 73% and 82.7%, respectively. There was not a statistical difference in activity between the control room and treatment room (P = 0.6041, x2 = 0.269). The activity index between the control room and treatment room was similar.

Trial 2: During the exposure period for the second trial, a total 47 pieces from 50 pieces were removed from the plates in the control room and 16 pieces from 20 pieces were removed from the plates in the treatment room over the 10- day trial period. Percent activity in the control room and treatment room was 80% and 94%, respectively. The activity index between the control room and treatment room was similar.

Observations

Visual counts were conducted for the control room and treatment room at approximately the same time twice a day to determine percent repellency during each trial. Visual observations were recorded at the same time for the control room and treatment room. All visual count data are presented in Table 2. Visual observations were used as a direct activity index of rodent activity and expressed as percent repellency. Data were tested against the null hypothesis that the test substance had no effect on the mean number of mice observed in either the control room or treatment room.

Table 2 Observation Counts and Room Preference after Fresh Cab Treatments.

	Samples	Total Counts	% Room Preference
Trial 1	Control	63	63
	Treatment	37	37
Trial 2	Control	31	31
	Treatment	69	69

Trial 1: During the first trial mice were visually observed in the control room 63% (n = 63) of the time and in the treatment room 37% (n = 37) of the time. Percent repellency was 63% for the first trial. The mean number of mice observed per observation period in the control room and treatment room was 3.15 and 1.85, respectively. The difference between the means was not statistically significant (P = 0.0848, t = 1.8 19) for trial 1.

Trial 2: During the second trial mice were visually observed in the control room 69% (n = 69) of the time and in the treatment room 31% (n =31) of the time. Percent repellency was 69% for the second trial. The mean number of mice observed per observation period in the control room and

cc: J.Fournier; BPPD Chron File; OHAD/ARS
M. Xue, BPPD, 02/10/10